IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	: 10/733,488	Confirmation No. 7675
Applicant	: Yaron ILAN, et al.	
Filed	: December 10, 2003	
Title	: REGULATION OF IMMUNE RESPONSES BY MANIPULATION OF INTERMEDIARY METABOLITE LEVELS	
TC/Art Unit	: 1648	
Examiner:	: Emily M. Le	
Docket No.	: 59046.000044 (Formerly Enz-64(D3))	
Customer No.	: 21967	

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

The above-identified application (the "Application") became abandoned for failure to file a timely and proper reply to the Office Action Election/Restriction, mailed on May 19, 2004, by the United States Patent and Trademark Office.

Applicants respectfully petition for revival of the Application. In order to obtain a grantable petition, Applicants are submitting the required items listed below:

1) PETITION FEE in the amount of $750.00 as set forth under 37 C.F.R. § 1.17(m);

2) A REPLY: The enclosed Response to Restriction Requirement provides a complete response to the outstanding non-final Office Action mailed on May 19, 2004;

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3) STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional.

In addition, Applicants have enclosed copies of the Office Action dated May 19, 2004; and Notice of Abandonment Under 37 C.F.R. § 1.53(f) or (g), dated December 9, 2004.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and § 1.17 associated with this communication or credit any overpayment to the deposit account of Hunton & Williams, Deposit Account Number 50-0206.

Respectfully submitted,

Date: 8/2/05

By: _____

Jessica L. Parezo
Registration No. 50,286

Christopher J. Nichols, Ph.D.
Registration No. 55,984

HUNTON & WILLIAMS LLP
Intellectual Property Department
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(202) 955-1500 (telephone)
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JLP/CJN:cdh

REMARKS

The outstanding Office Action requires that Applicants elect one of the following five (5) allegedly distinct inventions:

I. Claims 1-11, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 262;

II. Claims 12-24, drawn to a process of treating a disease with the administration of a reagent, classified in Class 435, subclass 262;

III. Claims 25-36, drawn to an *ex-vivo* process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 267;

IV. Claims 37-49, drawn to an *ex-vivo* process of treating a disease with the administration of a reagent, classified in Class 435, subclass 267;

V. Claims 50-62, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 262.

Applicants respectfully request reconsideration of the Restriction Requirement in view of the following remarks concerning the elections made herein.

First, restriction between inventions is only proper when a search burden exists for the Examiner to search all of the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions (see MPEP §803.01). In the instant case, all five Groups are drawn to methods of treating disease. Further, Groups I, III, and V are all drawn to administering a metabolite and Groups II and IV are both drawn to administering a reagents which increase metabolite levels. Therefore all five Groups are related in their use of metabolites for treating disease, either directly or indirectly. In addition, all five Groups are in classified in 435, with Groups I, II, and V sharing the same class and subclass

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	Enz-64(D3)	7675

28171 7590 12/09/2004

ENZO BIOCHEM, INC.
527 MADISON AVENUE (9TH FLOOR)
NEW YORK, NY 10022

EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment	Application No.	Applicant(s)	
	10/733,488	ILAN ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *19 May 2004*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

E.Le

Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
AU 1648

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	Enz-64(D3)	7675

7590 05/19/2004

Ronald C. Fedus, Esq.
Enzo Therapeutics, Inc.
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527 Madison Avenue (9th Floor)
New York, NY 10022-4304

EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/733,488	ILAN ET AL.
	Examiner	Art Unit
	Emily Le	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in class 435, subclass 262.

II. Claims 12-24, drawn to a process of treating a disease with the administration of a reagent, classified in class 435, subclass 262.

III. Claims 25-36, drawn to an ex-vivo process of treating a disease with the administration of a mammalian intermediary metabolite, classified in class 435, subclass 267.

IV. Claims 37-49, drawn to an ex-vivo process of treating a disease with the administration of a reagent, classified in class 435, subclass 267.

V. Claims 50-62, drawn to a process of treating a disease with the administration of a mammalian metabolite, classified in class 435, subclass 262.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I-II and V are directed to different methods requiring the different specific compounds. The invention of Group I requires the use of intermediary metabolites. The invention of Group II requires the use of reagents. The invention of Group III requires the use of metabolites. Intermediary metabolites, reagents, and metabolites are expected to differ from one another structurally and

biologically. The activities of an intermediary metabolite would not be the same as those for a reagent or a non-intermediary metabolite. Therefore, because of the compound that is employed in each group, the inventions of each group are patentably distinct from one another.

3. The inventions of Groups I-II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations. The invention of Groups I-II and V are directed to either an in vitro or in vivo use, however, the invention of Groups III-IV is directed to an ex vivo use.

4. In addition to an election to one of the above groups, Applicant is required to elect:

For Group I: Applicant must elect the type of mammalian intermediary metabolite: lipid or bioconjugates. If Applicant elects bioconjugates, Applicant must elect the type: glycolipids, lipoproteins, and glycoproteins. If Applicant elects glycolipids, monosaccharade ceramide, specifically, glucosyl ceramide and galactosyl ceramide will be examined.

Lipids are structurally distinct from bioconjugates. The biological activities of these molecules are not the same. Furthermore, concerning each of the listed bioconjugates, each of these listed bioconjugates is distinct from one another. There is no significant chemical structural similarity among the bioconjugates.

For Groups I-V: Applicant must further elect the disease: cancer, an infection, or immune dysfunction. If Applicant elects an infection, Applicant must elect viral or bacterial. If Applicant elects viral, then Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must elect diabetes type 1, diabetes type 2, rheumatoid arthritis, Crohn's disease, arteriosclerosis, or ulcerative colitis.

Inventions directed to each of the listed type of diseases are patentably distinct from one another because the diseases are independent and distinct from one another. The activities of a bacterial disease are different from those of a viral disease. The activities of an HBV infection are different from those of HCV and HIV. The activities of cancer are different from those of an infection and immune dysfunction. The activities of an immune dysfunction disease, such as, diabetes type 1, diabetes type 2, rheumatoid arthritis, Crohn's disease, arteriosclerosis, and ulcerative colitis are different from one another.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. The search required for Group I is not required for any of the other groups, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le
Emily Le

Shanon Foley
Patent Examiner, AU 1648